

- (c) a polynucleotide having the sequence set forth in SEQ ID NO: 1; and
- (d) a polynucleotide fully complementary to a polynucleotide of (a) through (c)

### REMARKS

Reconsideration of the present application is respectfully requested. Claims 2-18, 22-25, 27-53 and 64 are in the application for consideration.

Claims 3, 5, 12, and 14-17 remain rejected, newly added claim 64 is rejected, and newly amended claims 2, 4, 6-11, 13, 18, and 22 are rejected under 35 USC 112, first paragraph as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth in the previous office action. The Examiner states that a nucleic acid comprising a CycE polynucleotide having at least 80% identity to the entire coding region of SEQ ID NO:1 and complementary nucleotides thereof are not adequately described. The Examiner further states that it is unclear how the cyclin box and TTPXS structural element of a CycE polynucleotide relate to its function, or whether the structure and function of those elements would be preserved in an isolated nucleic acid having at least 80% identity to the entire coding region of SEQ ID NO:1. The Examiner goes on to say that it is unclear whether an isolated nucleic acid having at least 80% identity to the entire coding region of SEQ ID NO:1 would encode a polypeptide that binds to Cdk2.

Claim 64 has been amended to require "An isolated nucleic acid encoding a protein having Cyclin E activity". Amended claim 64 provides a functional requirement in addition to the structural requirement of an isolated nucleic acid having at least 80% identity to the entire coding region of SEQ ID NO:1.

The Examiner concludes that one skilled in the art could not predict the structure and function of isolated nucleic acids comprising a CycE polynucleotide

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having at least 80% identity to the entire coding region of SEQ ID NO:1 and complementary nucleotide thereof.

Predictability and undue experimentation are discussed in detail below with reference to enablement.

Predictability is discussed in detail below under enablement. "To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that the inventor invented the claimed invention", *Regents of University of California v. Eli Lilly & Co.* 119 F.3d 1559, 43 USPQ2d 1398 (Fed Cir. 1997) quoting *Lockwood v. American Airlines, Inc.*... (Fed Cir. 1997) and *In re Gosteli*... (Fed Cir. 1989). The description must clearly allow persons of ordinary skill in the art to recognize that the inventor invented what is claimed. Thus, an applicant complies with the written description requirement by describing the invention with all its claimed limitations by using such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention.

It is submitted that these requirements are met in the present application. The nucleotide sequences disclosed provide the necessary structure in the application. One skilled in the art can readily determine a sequence that has 80% sequence identity to the disclosed sequences. Therefore, one skilled in the art would understand that the inventors had possession of the invention at the time of filing.

Original claims 3, 5, 12, 14-17, 24-25, and 27-53 remain rejected, newly added claim 64 is rejected, and newly amended claims 2, 4, 6-11, 13, 18, 22, and 23 are rejected under 35 USC 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The Examiner maintains that the scope of the invention is not enabled. The Examiner states that the specification does not reasonably provide

enablement for a CycE polynucleotide having at least 80% identity to the entire coding region of SEQ ID NO:1 and complementary nucleotides thereof. The Examiner concludes that the scope of the invention is not enabled because of the unpredictability of determining the function of isolated nucleic acids homologous to SEQ ID NO:1, and because of the unpredictability of altering the phenotype of a plant by transforming it with isolated nucleic acids homologous to SEQ ID NO:1.

When determining the quantity of experimentation necessary, the focus is not on the amount of experimentation necessary to practice the entire genus, but the amount of experimentation required to practice any particular member. This concept is the central holding of *In re Wands* where the claims read on the use of any IgM antibody that possessed a particular binding affinity. The *Wands* court recognized that it would require an infinite amount of experimentation to obtain every single possible IgM antibody that could be generated with the specified affinity. Accordingly, the court focused on the amount of experimentation necessary to practice any particular IgM antibody with the recited binding affinity and not the amount of experimentation required to practice the entire genus. This focus is further supported by the multitude of chemical patents that have issued with generic claims reading on tens to hundreds of thousands of individual members.

The question then becomes how much experimentation is required to create the claimed invention. Applicants submit that no more than routine experimentation is required. This may be accomplished by the examples and methods within the present application and within the technical, scientific, skill in the art.

Applicants assert the present invention is disclosed in a way that one skilled in the art will be able to practice it without an undue amount of experimentation. *In re Borkowski*, 422 F.2d 904, 908, 164 USPQ 642, 645 (CCPA 1970). Applicants submit that they have fully described the present invention as claimed by teaching both how to make and how to use the invention. Therefore, one of ordinary skill

could use Applicants' teachings to determine if a sequence conforms to the present claims.

The USPTO carries the initial burden to establish a reasonable basis for questioning the enablement provided for the claimed invention. As stated in *In re Wright*, 99, F.2d 1557, 27 USPQ2d 1510 (Fed. Cir. 1993); MPEP § 2164.04, the enablement requirement is satisfied if the specification describes any method for making and using the claimed invention that bears a "reasonable correlation" to the entire scope of the claims. Applicants submit that this has been accomplished in the present application.

Original claims 3, 5, 12, and 14-17 remain rejected, newly added claim 64 is rejected, and newly amended claims 2, 4, 6-11, 13, 18, and 22 are rejected under 35 USC 101 as not being supported by a specific and substantial utility, for the reasons of record set forth in the previous office action. The Examiner maintains that the invention does not have a specific and substantial utility because it is unclear whether the expression of a functional CycE nucleic acid in a host cell would result in an increase in the G1 to S transition of the host cell, or an increase in transformation efficiency of the host cell.

Applicants have provided specific and substantial utility of the present claimed invention in both the application and the 1.132 Declaration submitted in the previous response. In summary the present claimed sequences exhibit a high level of homology, contain conserved regions, and complement G1 cyclin deficient yeast. These are all indicative of a CycE polynucleotide. The function of mammalian CycE genes has been demonstrated in the art. The Examiner has not rebutted these conclusions with anything that would lead one to doubt these conclusions.

The withdrawal of the rejection of claims 18 and 19 under 35 USC 101 as being directed to non-statutory subject matter is noted with appreciation.

The withdrawal of the rejection of claims 1-12 under 35 USC 102(b) as being anticipated by Kende *et al.* is noted with appreciation.

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Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned **"Version with markings to show changes made."**

In view of the above amendments and comments withdrawal of the outstanding rejections and allowance of all of the remaining claims is respectfully requested.

Respectfully submitted, -



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**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

**In the Claims:**

Claim 64 has been amended as follows:

64. (Amended) An isolated ~~Cyclin E nucleic acid comprising~~ nucleic acid encoding a protein having Cyclin E activity, wherein the nucleic acid comprises a member selected from the group consisting of:
- (a) a polynucleotide that encodes a polypeptide of SEQ ID NO: 2;
  - (b) a plant Cyclin E polynucleotide having at least 780% identity to the entire coding region of SEQ ID NO: 1, wherein the % identity is determined by GCG/bestfit GAP 10 program using a gap creation penalty of 50 and a gap extension penalty of 3;
  - (c) a polynucleotide having the sequence set forth in SEQ ID NO: 1; and
  - (d) a polynucleotide fully complementary to a polynucleotide of (a) through (c).